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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,052	03/22/2006	Giovanni Meazza	163-689	8978
7590 James V Costigan Hedman & Costigan 1185 Avenue of the Americas New York, NY 10036-2601			EXAMINER HAYLIN, ROBERT H	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 07/14/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/573,052

**Applicant(s)**

MEAZZA ET AL.

**Examiner**

ROBERT HAVLIN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### DETAILED ACTION

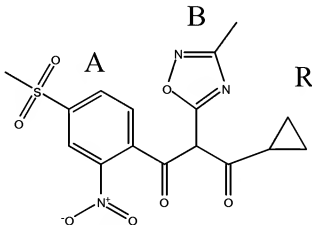
**RCE:** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/10 has been entered.

**Status of the claims:** Claims 2, 13-17 are currently pending.

**Priority:** This application is a 371 of PCT/EP04/10653 (09/21/2004) and claims foreign priority to ITALY MI2003A 001855 (09/29/2003).

### *Election/Restrictions*

- Applicant previously elected Group I (product of Formula I) and the species of compound No. 22 (Table 1 on page 163):



1-cyclopropyl-2-(3-methyl-1,2,4-oxadiazol-5-yl)-3-(4-(methylsulfonyl)-2-nitrophenyl)propane-1,3-dione

As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP § 803.02.

#### **RESPONSE TO APPLICANT'S REMARKS / AMENDMENTS**

##### ***Claim Rejections - 35 USC § 102***

2. Claims 2, 13, and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by McElvain et al. (CAPLUS Abstract (Accession # 1941:42347) of: Journal of the American Chemical Society (1941), 63, 2192-7).

The prior art teaches the following compound:



Which anticipates the claim when "A" is furyl, "B" is furyl, and "R" is hydrogen as described by formula I.

Applicant has amended claim 17 to delete hydrogen as an alternative for "-R" thereby avoiding the prior art. This rejection is **withdrawn**.

***Claim Rejections - 35 USC § 112***

3. Claims 2, 13, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim has conflicting definitions because it is not clear how "D" can be "monocyclic" and "polycyclic" at the same time.

Applicant has appropriately amended the claim to avoid the rejection.

Accordingly, the rejection is **withdrawn**.

**NEW CLAIM REJECTIONS**

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, and 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds demonstrated as being useful and those reasonably related, does not reasonably provide enablement for the asserted utility of the entirety of the claim scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Particularly relevant to the instant case is the issue as to whether the specification provides embodiments allowing use of the claimed invention without

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requiring undue experimentation by one of ordinary skill in view of the highly unpredictable nature of using compounds as bioactive agents or herbicides.

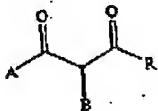
"[An inventor] must not be permitted to achieve . . . dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Accordingly, the critical element here how broad the claims are compared to the level of unpredictability in the art.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

*Nature of Invention.* The nature of the invention involves biologically active compounds, specifically herbicides.

*Scope of the Invention.* The scope of the invention is a genus of compounds of formula



I ( ) having in excess of billions of species.

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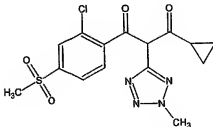
*State of the Art and Level of Skill in the Art.* Although the level of skill in the art is very high, affecting biological systems with chemical compounds is a very unpredictable art. For example as described in Table 1 of Harris et al. (Pestic. Sci. 1980, 11, 439-44, cited by applicant) very small changes in structure can have large unpredictable effects on the biological activity of a compound. Similarly, Lee et al. (Pestic. Sci. 1998, 54, 377-384) demonstrates that those of skill in the art must resort to a form of trial and error due to the unpredictability of herbicidal activity.

*Number of Working Examples and Guidance Provided by Applicant.* The applicant provides an experimental demonstration for the following three compounds wherein only "B" varies in structure:

Compounds 6, 7, 11:

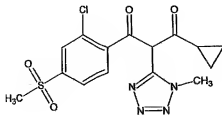
EXAMPLE 11

Synthesis of 1-[2-chloro-4-(methylsulphonyl)phenyl]-3-cyclopropyl-2-(2-methyl-2H-tetrazol-5-yl)propane-1,3-dione (Compound N° 6, corresponding to compound N° 610 in table 2)



EXAMPLE 12

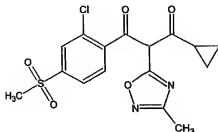
Synthesis of 1-[2-chloro-4-(methylsulphonyl)phenyl]-3-cyclopropyl-2-(1-methyl-1H-tetrazol-5-yl)propane-1,3-dione (Compound N° 7, corresponding to compound N° 605 in table 2)



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EXAMPLE 18

Synthesis of 1-[2-chloro-4-(methylsulphonyl)phenyl]-3-cyclopropyl-2-(3-methyl-1,2,4-oxadiazol-5-yl)propane-1,3-dione (Compound N° 11, corresponding to compound N° 385 in table 2).



*Unpredictability of the Art and Amount of Experimentation.* The art of using compounds as bioactive agents as herbicides is highly unpredictable as shown in Harris and Lee. In nearly every case, the skilled artisan could not predict *a priori* whether a given compound would be active as a herbicide. When small variations in structure such as the addition of a methyl group has radical effects on activity, without specific guidance or correlations indicating how the structure of species affects its utility, the scope of enablement is constrained to compounds showing substantial similarity to those actually demonstrated to be useful. Furthermore, there would be a huge amount of undue experimentation required in order to synthesize and screen the billions of compounds within the claimed scope.

Considering the above factors, the claims are clearly not enabled for the full scope of the compounds claimed. The examiner recommends either amending the claim scope to only those compounds closely resembling the compounds actually tested (i.e. where "A" and "R" are as in the compounds cited above) and disclosed in the specification or provide additional data and/or structural correlations to guide one of ordinary skill in the art to compounds possessing the asserted utility.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:



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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The proviso conditions spanning pages 13-15 of the amended claims contains numerous conditions which fall outside of the present claim scope which creates confusion as to whether applicant intends to claim subject matter beyond those positively recited. For example, there are numerous occurrences where a set of A, B, and R are proviso-ed where B is phenyl, however, according to the positive recitations in the claim it appears that B cannot be phenyl. One of ordinary skill in the art would be confused by such conflicting definitions of the scope of the claims such that it would be considered vague and ambiguous. Applicant should either delete the confusing provisos from the claims or amend the positive recitations such that it encompasses the proviso.

8. Claims 2, and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's use of commas and semicolons in the claims is inconsistent and creates confusion with respect to what defines a particular element or sub-element. For example, in claim 17, the definition of "-A represents:" utilizes semicolons between what appear to be alternative substituents for aryl; however, an alternative interpretation is that as a result of the use of a semicolon, applicant intends to delineate alternatives for

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"-A" itself. The examiner recommends use of commas and/or indentation in accordance with MPEP § 608.01. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP 608.01(i)-(p).

9. Claims 2, and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The quality of the claims provided by applicant on 4/20/10 are so poor that many of the subscripts and other parts of the claims are so difficult to read that prior versions of the claims need to be consulted. For example, in claim 17:

**-B represents a  $D-(R_x)_n$  group;**

is nearly impossible to determine what the subscript refers to; It could be "o" "n".

#### ***Conclusion***

The claims are not in condition for allowance.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

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If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626